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| 10/502,420 | 08/26/2005 | Richard O Chen | 27763-705.831 | 5778 |

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| EXAMINER | |
|---|---|
| CLOW, LORI A | |
| ART UNIT | PAPER NUMBER |
| 1631 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/502,420 | CHEN ET AL. | |
| | Examiner | Art Unit | |
| | LORI A. CLOW | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *1-25 and 45-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-44 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**EXAMINER'S AMENDMENT**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 July 2010 has been entered.

Applicants' response, filed 7 July 2010, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-57 are pending. Claim1-25 and 45-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 February 2009. Claims 26-44 and 54-57 are under exam herein.

**Priority**

The instant application claims priority to US 60/353,176, filed 4 February 2002 and to US 60/421,772, filed 29 October 2002. Priority to 60/353,176 is hereby denied, as the provisional application fails to disclose the instantly claimed invention. Specifically, the provisional application does not disclose profile models and the building of profiles according to genomics information that is identified for overlap and statistically analyzed to establish

biological interactions. Priority to 60/421,772 is acknowledged. For purposes of applying prior art, the priority date accorded herein is 29 October 2002.

It is noted that the Petition to Accept Unintentionally Delayed Benefit Claim under 35 USC 119(e), 120, 121, and 356(c) has been granted.

**Information Disclosure Statement**

The Information Disclosure Statement filed 8 July 2010 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-38, 40, 42-44 and 54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by 2002/0194201 (Wilbanks et al.).

The instant claims are drawn to a computer system for evaluating user-supplied genomics data with a computer that has a structured database to store and access genomics information and the computer computes complex relationships among genes and/or gene products and the computer is configured to define a profile model, build a collection of profiles using the

genomics information, identify overlaps of genomics data and statistically analyze profiles with genomics information.

In regard to claim 26, Wilbanks et al. teach integrated biological/chemical databases formed by establishing entity-relationship models for each of the databases and identifying related entities in the relationship models (abstract). Wilbanks et al. further teach the identification of identical entities, thus teaching overlapping information (paragraph 0009). The plurality of databases represents an ontology that is integrated to create an ontology network. Wilbanks et al. teach a query of results stored as at least one new relationship in the entity-relationship model and the establishment of a confidence level that is assigned to at least one of the relationships (paragraph 0013). The biological databases include gene and protein sequence databases, genomic databases, gene prediction databases (paragraph 0052, 0132, 0133), among others. Wilbanks et al. teach cluster comparisons for data prediction and groupings (paragraph 0087).

In regard to claim 27, Wilbanks et al. teach a priori data built in to the system (paragraph 0069).

In regard to claim 28, Wilbanks et al. teach profiles generated from graph structures (DWGs; paragraph 0086).

In regard to claim 29, Wilbanks et al. teach data query (paragraph 0013).

In regard to claim 30, Wilbanks et al. teach probability calculations (likelihood of success predictions; paragraph 0084, 0132, 0133).

In regard to claim 31, Wilbanks et al. teach databases with gene, gene product, and biological process information (paragraphs 0052 and 0087).

In regard to claim 32, Wilbanks et al. teach differential gene expression data (paragraph 0087).

In regard to claim 33, Wilbanks et al. teach disease data (paragraph 0112).

In regard to claim 34, Wilbanks et al. teach profile generation criterion using biological processes (entire document, 0135).

In regard to claim 35, Wilbanks et al. teach profile generation from nodes (paragraph 0089).

In regard to claim 36, Wilbanks et al. teach nodes that are genes, proteins, gene families etc… (paragraph 0089).

In regard to claim 37, Wilbanks et al. teach comparison to generate biological associations of the different profiles (paragraphs 0018, 0052, 0065, 0084, 0087).

In regard to claim 38, Wilbanks et al. teach data linkages (paragraph 0065).

In regard to claim 40, Wilbanks et al. teach data annotation and associations that include cellular processes or disease processes (paragraphs 0087, 0088, 0112).

In regard to claim 42, Wilbanks et al. teach classifications of profiles from ontology information (paragraphs 0009, 0018, 0087).

In regard to claim 44, Wilbanks et al. teach profile models using different criterion wherein the a priori knowledge is represented by associated databases and the data can be merged/overlaid (paragraphs 0069, 0130)..

In regard to claim 54, Wilbanks et al. teach gene associations for disease using the relationship finder (paragraph 0112).

In regard to claim 55, Wilbanks et al. teach candidate development compounds (paragraph 0120).

In regard to claim 56, Wilbanks et al. teach disease-related pathways (paragraph 0112, 0120).

In regard to claim 57, Wilbanks et al. teach gene expression linked to markers which are linked to disease states (paragraphs, 0120, 0193-0195).

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**1.** Claims 39 and 41are rejected under 35 U.S.C. 103(a) as being unpatentable over 2002/0194201 (Wilbanks et al.), as applied to claims 26 and 40 above, in further view of Karp et al. (TIBTECH (1999) Vol. 17, pages 275-281; IDS reference).

In regard to claim 26, Wilbanks et al. teach integrated biological/chemical databases formed by establishing entity-relationship models for each of the databases and identifying related entities in the relationship models (abstract). Wilbanks et al. further teach the identification of identical entities, thus teaching overlapping information (paragraph 0009). The plurality of databases represents an ontology that is integrated to create an ontology network. Wilbanks et al. teach a query of results stored as at least one new relationship in the entity-relationship model and the establishment of a confidence level that is assigned to at least one of the relationships (paragraph 0013). The biological databases include gene and protein sequence databases, genomic databases, gene prediction databases (paragraph 0052, 0132, 0133), among others. Wilbanks et al. teach cluster comparisons for data prediction and groupings (paragraph 0087).

In regard to claim 40, Wilbanks et al. teach data annotation and associations that include cellular processes or disease processes (paragraphs 0087, 0088, 0112).

Wilbanks et al. do not specifically teach display of data using GUI, however Karp et al. teach integrated pathway-genome databases for drug discovery in which graphical user interface is used that includes a visualization tool for all data types (page 278). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the GUI

of Karp et al. to display the ontology database profiles of Wilbanks et al., as GUI is a well-known interface for user-friendly operations. Both Karp et al. and Wilbanks et al. use genome databases to establish relational information.

**2.** Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over 2002/0194201 (Wilbanks et al.), as applied to claims 26 above, in further view of Qu et al. (Intelligent Systems in Biology (2002) March/April, pages 21-27; IDS reference; previously cited).

In regard to claim 26, Wilbanks et al. teach integrated biological/chemical databases formed by establishing entity-relationship models for each of the databases and identifying related entities in the relationship models (abstract). Wilbanks et al. further teach the identification of identical entities, thus teaching overlapping information (paragraph 0009). The plurality of databases represents an ontology that is integrated to create an ontology network. Wilbanks et al. teach a query of results stored as at least one new relationship in the entity-relationship model and the establishment of a confidence level that is assigned to at least one of the relationships (paragraph 0013). The biological databases include gene and protein sequence databases, genomic databases, gene prediction databases (paragraph 0052, 0132, 0133), among others. Wilbanks et al. teach cluster comparisons for data prediction and groupings (paragraph 0087).

Wilbanks et al. do not specifically teach the kind of statistical significance testing used that includes null hypothesis over probability. However, Qu et al. teach a system and method for integrating multidimensional data for relationship inference in genomics systems by implementing data from gene ontologies (page 22, column 3). Qu et al. also teach the

calculation of relationship inference by statistical methods such as cluster analysis using hierarchical clustering employing the Pearson correlation coefficient to construct a relationship tree (page 24, column 3), showing that, in addition to the algorithms used by Wilbanks et al., various other statistical methodology may be employed to analyze relationship data for overlapping pathways, therefore making it prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the well-know statistical method of null hypothesis and probability distribution to analyze statistical significance of pathway overlap. One would have had a reasonable expectation of success in doing so because such databases were known and developed at the time of the invention and readily available for scientific use. Wilbanks et al. teach information gathering from a myriad of sources, including literature based findings, multiple databases and other findings (Figure 3).

**Conclusion**

No claims are allowed.

The outstanding rejections under 35 USC 12 and 103 from the previous Office Action, over Chandra and Chandra and Qu, respectively, are hereby withdrawn in view of the corrected priority claim.

**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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September 7, 2010
/Lori A. Clow, Ph.D./
Primary Patent Examiner
Art Unit 1631